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EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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08/06/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,678	<b>Applicant(s)</b> TANAHASHI ET AL.	
	<b>Examiner</b> ANN Y. LAM	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 15-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites in line 10 "the tube forming a part of the circuit". The claim lacks an antecedent basis for this limitation, and thus it is not clear to which part (or tube) of the circuit is being referred.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al., 6,348,156, in view of Hedrick et al., 7,514,075.

Vishnoi et al. disclose a blood separation system comprising a device for separating whole blood into red blood cells and plasma, such blood separation devices

Art Unit: 1641

being for example a membrane blood separation device (col. 6, lines 60-63.) The system includes a sensing assembly outside the device, which comprises a first sensor to sense a characteristic of plasma and a second sensor adjacent to the first sensor to sense a characteristic of red blood cells. A fluid circuit is coupled to the device and includes a plasma collection tube for conveying a flow of plasma from the device and a red blood cell collection tube for conveying a flow of red blood cells from the device. According to this aspect of the invention, the tubes are held in a fixture, which is movable into releasable engagement with the sensing assembly. The fixture holds the plasma collection tube and the red blood cell collection tube in adjacent sensing alignment with, respectively, the first sensor and the second sensor. See column 3, lines 15-31. It is also disclosed that in one embodiment, the fluid circuit includes a whole blood inlet tube for conveying a flow of whole blood into the device. In this embodiment, the fixture also holds the whole blood inlet tube. The fixture thereby serves to gather and hold the whole blood inlet tube, the plasma collection tube, and the red blood cell collection tube in a bundle. See column 3, lines 32-37. Vishnoi et al. disclose that the system can be provided such that it maintains a closed blood processing environment (col. 10, line 63 to column 11, line 10.)

Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. See col. 12, lines 16-29.

Art Unit: 1641

As to claims 1 and 12, the closed system disclosed by Vishnoi et al. is equivalent to Applicant's claimed fractionation device. The whole blood inlet tube is equivalent to the claimed supply part for loading raw liquid. The chamber housing the membrane is equivalent to the claimed filtration part for filtering some of the solutes. The pneumatic pump is equivalent to the claimed flow pump.

Applicant has amended the claims to recite a concentration part that is connected to the filtration part by a flow channel for increasing the concentration of one or more solutes in the filtrate received from the filtration part to produce a concentrated solution. While the Vishnoi et al. filtration part increases the concentration of the solutes, there is no disclosure of another part that increases the concentration of one or more solutes in the filtrate received from the filtration part. However, this limitation is taught by Hedrick et al.

Hedrick et al. teach a system that includes various chambers coupled together coupled together via one or more conduits such that fluids containing biological material may pass from one chamber to another while maintaining a closed, sterile fluid/tissue pathway. The conduits may be flexible tubings and should also be capable of withstanding positive pressure which is generated by, for example, a positive displacement pump, which may be used in the system. Column 10, line 32 to column 11, line 3.

It is also disclosed that the system may also include a plurality of filters 36. In certain embodiments, the filters may be within a chamber of the system 28. Different

Art Unit: 1641

chambers within the system may be comprised of different filters. The filters are effective to separate the regenerative cells, e.g., stem cells and/or progenitor cells, from undesirable cells and disaggregation agents that may be used in accordance with the system. In one embodiment, a filter assembly 36 includes a hollow fiber filtration device. In another embodiment, a filter assembly 36 includes a percolative filtration device. In yet another embodiment, the system comprises a combination of these filtering devices. The filtration functions of the present invention can be two-fold, with some filters removing things from the final concentration such as collagen, free lipid, free adipocytes and residual collagenase, and with other filters being used to concentrate the final product. The filters of the system may be comprised of a plurality of pores ranging in diameters and/or length from 20 to 800 .mu.m. In a preferred embodiment, the collection chamber 20 has a prefixed filter 28 with a plurality of pores ranging from 80 to 400 .mu.m. In another preferred embodiment, the collection chamber 20 has a prefixed filter 28 with a plurality of 265 .mu.m pores. Column 11, line 53 to column 12, line 12.

After the adipose tissue is processed, the resulting regenerative cells are substantially free from mature adipocytes and connective tissue. Accordingly, the system of the present invention generates a heterogeneous plurality of adipose derived regenerative cells which may be used for research and/or therapeutic purposes. Column 10, lines 1-12. It is noted that the illustrated embodiments are presented as examples only. Column 10, lines 27-36.

Art Unit: 1641

It is emphasized that Hedrick et al. teach that the device can include more than one filtration device for removing particular materials from the final concentration, and/or to concentrate the final product. The skilled artisan would have recognized that the Vishnoi et al. device can be modified to incorporate additional filter(s) for the purpose of removing unwanted materials and/or concentrate the final product, as taught by Hedrick et al., as would be desirable in improving the separation of red blood cells in the Vishnoi et al device. The skilled artisan would have had the knowledge to utilize the appropriate tubings and connections to produce such a modified Vishnoi et al. device for this purpose, and thus would have had reasonable expectation of success. The part of this modified Vishnoi et al. device that is on the side of the final filter is equivalent to the claimed concentration part, since it is the part of the device with increased concentration of red blood cells (solutes) in the filtrate received from the first filter (the claimed filtration part).

As to claim 2, the red blood cell collection tube is equivalent to the claimed recovery part for recovering concentrated solution obtained in the concentration part. Moreover, because Vishnoi et al. disclose that the device can be a closed circuit, therefore, any parts of the device form a closed circuit. It is noted that there is no limitations regarding how the various claimed parts are connected such that they form a closed circuit.

As to claim 4, the separation membrane of Vishnoi et al. is equivalent to the claimed filtration apparatus.

Art Unit: 1641

As to claim 6, a pump as claimed is disclosed by Vishnoi et al. (ccol. 12, lines 16-29.)

As to claim 7, the plasma collection tube disclosed by Vishnoi et al. is equivalent to the claimed container.

Claims 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of Hedrick et al., 7,514,075, and further in view of O'Connor et al., 7,074,327.

Vishnoi et al. has been discussed above (see discussion of claim 1.) However, Vishnoi et al. do not disclose that the total inner capacity of the closed circuit is 50 mL or lower. However, microfabrication of laboratory devices is well known in the art and its benefits are also well known, as shown by O'Connor et al. in disclosing that microfluidic technology allows for use of very small quantities and thus less liquid waste and reduced cost (col. 1, line 59 to col. 2, line 15.) It would have been obvious to one of ordinary skills in the art at the time the invention was made to scale down the size of the Vishnoi et al. system since it is well known, as shown by O'Connor et al., that providing a device on a small scale provides the benefit of reducing waste and cost. Providing the capacity in the specific range claimed by Applicant is within a workable range.

As to claim 9, the Vishnoi et al. apparatus produced on a small scale is equivalent to a cartridge.



Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of Hedrick et al., 7,514,075, and further in view of Komatsu et al., 5,976,433.

Vishnoi et al. has been discussed above regarding claim 1. However, Vishnoi et al. do not disclose that the filtration apparatus is a module having hollow fiber membranes.

However, Komatsu et al. disclose slit-like micropores mean micropores thinly extending in the direction of hollow fiber axis (col. 3, lines 24-33.) The PVA-based hollow fiber membranes, having sharp fractionating capability, is effective in separating different substances having close particle sizes and can be used for blood filtration and separation of plasma among other uses (col. 6, lines 53-61.)

It would have been obvious to one of ordinary skills in the art at the time the invention was made to combine the teachings of Vishnoi et al. and Komatsu et al. to provide hollow fiber membranes taught by Komatsu et al. as the specific type of filter for plasma separation in the Vishnoi et al. invention because Komatsu et al. disclose that such material is effective in separating different substances having close particle sizes and can be used for blood filtration and separation of plasma. The skilled artisan would have had reasonable expectation of success because Vishnoi et al. do not limit the invention to only a separation matrix and thus the skilled artisan would expect that

Art Unit: 1641

the device can be used with other plasma separating elements, such as that disclosed by Komatsu et al.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vishnoi et al. , 6,348,156, in view of Hedrick et al., 7,514,075, and further in view of Mendel-Hartvig et al., 7,018,847.

Vishnoi et al. has been discussed above. However, Vishnoi et al. do not disclose a buffer part for buffering the volumetric alteration at the time of loading raw liquid.

However, this is taught by Mendel-Hartvig et al. It is disclosed by Mendel-Hartvig et al. a membrane strip on a polyester backing, a sample filter with a blood cell/plasma separation membrane, and a buffer pad containing buffer. See column 8, lines 57-65. It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide a buffer pad as disclosed by Mendel-Hartvig et al. along with the plasma separation membrane of Vishnoi et al. because Mendel-Hartvig et al. disclose that this is a known technique employed with a blood cell/plasma separation membrane. The skilled artisan would have recognized the benefits of providing a buffer for maintaining the desired pH.

Art Unit: 1641

Claims 10 and 11 are being unpatentable over Vishnoi et al. , 6,348,156, in view of Hedrick et al., 7,514,075 and Mendel-Hartvig et al., 7,018,847, as applied to claim 8 above, and further in view of Leader et al., 6,193,864.

Vishnoi et al. and Mendel-Hartvig et al. have been discussed above. However, neither patents disclose a flow pump that is a tube with a rotating rotor and a roller installed in a rotating manner in the outer circumference of the rotor and a portion of the outer wall of the device or cartridge is a squeezing member for squeezing a part of the flow channels of the circuit, as recited in claim 10. These limitations however are disclosed by Leader et al. as discussed further below.

It is noted however that Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprising positive and negative pneumatic pressure. Other types of fluid pressure can be used. See col. 8, lines 9-16.

Vishnoi et al. disclose that the cassette 28 can take various forms. As illustrated (see FIG. 6), the cassette 28 comprises an injection molded body 188 having a front side 190 and a back side 192. Flexible diaphragms 194 and 196 overlay both the front side 190 and back sides 192 of the cassette 28, respectively. The cassette body 188 is preferably made of a rigid medical grade plastic material. The diaphragms 194 and 196 are preferably made of flexible sheets of medical grade plastic. The diaphragms 194 and 196 are sealed about their peripheries to the peripheral edges of the front and

Art Unit: 1641

back sides of the cassette body 188. Interior regions of the diaphragms 194 and 196 can also be sealed to interior regions of the cassette body 188. Column 8, lines 24-40.

Figure 6 shows, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36 (see FIG. 1). The cassette 28 is, in use, mounted in the pump and valve station 30. The pump and valve station 30 apply positive and negative pneumatic pressure upon the cassette 28 to direct liquid flow through the circuit. See column 8, lines 17-23. Figure 22 also shows, each actuator PA1 to PA4 and VA1 to VA23 includes a port 228. The ports 228 convey positive or negative pneumatic pressures from the source in a sequence governed by the controller 16. These positive and negative pressure pulses flex the front diaphragm 194 to operate the pump chambers PP1 to PP4 and valve stations V1 to V23 in the cassette 28. This, in turn, moves blood and processing liquid through the cassette 28. See col. 12, lines 16-29.

Moreover, Vishnoi et al. disclose that a cassette holder 216 preferably includes an integral elastomeric membrane 232 (see FIG. 6) stretched across a manifold assembly 226. The membrane 232 serves as the interface between the piston element 226 and the diaphragm 194 of the cassette 28, when fitted into the holder 216. The membrane 232 may include one or more small through holes (not shown) in the regions overlying the pump and valve actuators PA1 to PA4 and V1 to V23. The holes are sized to convey pneumatic fluid pressure from the manifold assembly 226 to the cassette diaphragm 194. Still, the holes are small enough to retard the passage of liquid. The membrane 232 forms a flexible splash guard across

Art Unit: 1641

the exposed face of the manifold assembly 226. The splash guard membrane 232 keeps liquid out of the pump and valve actuators PA1 to PA4 and VA1 to VA23, should the cassette diaphragm 194 leak. The splash guard membrane 232 also serves as a filter to keep particulate matter out of the pump and valve actuators of the manifold assembly 226. Column 12, lines 30-49.

Moreover, Leader et al. disclose a cartridge for analyzing blood wherein the device includes a peristaltic roller pump for pumping fluids. The peristaltic roller pump includes a roller 206 that massages the pump tube 136. The roller 206 applies areas of alternating greater and lesser pressure to the pump tube 136, causing those portions of the pump tube 136 that lie over an area of greater pressure to be internally constricted and those areas of the pump tube 136 that lie over an area of lesser pressure to be relaxed to essentially the full unstressed diameter of the channel through the interior of the pump tube 136. As the roller 206 rotates, the areas of alternating greater and lesser pressure traverse the pump tube 136 to generate a peristaltic action in the pump tube 136. See column 8, lines 31-44.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide the peristaltic roller pump as disclosed by Leader et al. in the Vishnoi et al. device because Vishnoi et al. do not limit the type of pumping mechanism that can be used, and specifically state that positive and negative pneumatic pressure is illustrated but that other types of fluid pressure can be used (column 8, lines 9-16.) Thus the skilled artisan would have looked to the art for the various suitable pumping mechanisms, such as that disclosed by Leader et al., and

Art Unit: 1641

modify the Vishnoi et al. device accordingly for incorporating the pumping mechanism. In such modification, the skilled artisan would have recognized that the channels within the Vishnoi et al. cassette are comparable to the pump tube of Leader et al. and thus can be substituted by the pump tube. Moreover, the skilled artisan would have recognized that the diaphragm on the Vishnoi et al. cassette can remain in the modified device since it forms the cassette. In the modified cassette and pumping mechanism, the pump tube is equivalent to the claimed tube forming a part of the circuit. The diaphragm is equivalent to the claimed outer wall of the cartridge (cassette) for squeezing the pump tube beneath. The skilled artisan would have recognized that for the diaphragm to transfer the pressure to the pump tube, the tube can be disposed on the diaphragm (equivalent to the claimed outer wall.) (It is noted that in claim 13, the pump tube is also the "tube of the roller type tube pump"). Alternatively, the elastomeric membrane 232 is equivalent to the outer wall of the cartridge.

As to claim 11, it is understood that the roller and tube pump move relatively to each other. It would have been obvious to the skilled artisan to move one of the other in order to effect this relative motion for performing the pumping mechanism.

Claims 13 and 14 are rejected being unpatentable over Vishnoi et al. , 6,348,156, in view of Hedrick et al., 7,514,075, and further in view of Leader et al., 6,193,864.

Vishnoi et al. has been discussed above (see discussion of claim 1 above) and are equally applicable here. However, Vishnoi et al. do not disclose a roller pump and a

Art Unit: 1641

squeezing member for squeezing the tube of the roller tube pump. These limitations however are disclosed by Leader et al. as discussed further below.

It is noted however that Vishnoi et al. disclose that the programmable fluid circuit 46 is implemented by use of a fluid pressure actuated cassette 28 (see FIG. 6). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprising positive and negative pneumatic pressure. Other types of fluid pressure can be used. See col. 8, lines 9-16.

Vishnoi et al. disclose that the cassette 28 can take various forms. As illustrated (see FIG. 6), the cassette 28 comprises an injection molded body 188 having a front side 190 and a back side 192. Flexible diaphragms 194 and 196 overlay both the front side 190 and back sides 192 of the cassette 28, respectively. The cassette body 188 is preferably made of a rigid medical grade plastic material. The diaphragms 194 and 196 are preferably made of flexible sheets of medical grade plastic. The diaphragms 194 and 196 are sealed about their peripheries to the peripheral edges of the front and back sides of the cassette body 188. Interior regions of the diaphragms 194 and 196 can also be sealed to interior regions of the cassette body 188. Column 8, lines 24-40.

Figure 6 shows, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36 (see FIG. 1). The cassette 28 is, in use, mounted in the pump and valve station 30. The pump and valve station 30 apply positive and negative pneumatic pressure upon the cassette 28 to direct liquid flow through the circuit. See column 8, lines 17-23. Figure 22 also shows,

Art Unit: 1641

each actuator PA1 to PA4 and VA1 to VA23 includes a port 228. The ports 228 convey positive or negative pneumatic pressures from the source in a sequence governed by the controller 16. These positive and negative pressure pulses flex the front diaphragm 194 to operate the pump chambers PP1 to PP4 and valve stations V1 to V23 in the cassette 28. This, in turn, moves blood and processing liquid through the cassette 28. See col. 12, lines 16-29.

Moreover, Vishnoi et al. disclose that a cassette holder 216 preferably includes an integral elastomeric membrane 232 (see FIG. 6) stretched across a manifold assembly 226. The membrane 232 serves as the interface between the piston element 226 and the diaphragm 194 of the cassette 28, when fitted into the holder 216. The membrane 232 may include one or more small through holes (not shown) in the regions overlying the pump and valve actuators PA1 to PA4 and V1 to V23. The holes are sized to convey pneumatic fluid pressure from the manifold assembly 226 to the cassette diaphragm 194. Still, the holes are small enough to retard the passage of liquid. The membrane 232 forms a flexible splash guard across the exposed face of the manifold assembly 226. The splash guard membrane 232 keeps liquid out of the pump and valve actuators PA1 to PA4 and VA1 to VA23, should the cassette diaphragm 194 leak. The splash guard membrane 232 also serves as a filter to keep particulate matter out of the pump and valve actuators of the manifold assembly 226. Column 12, lines 30-49.

Moreover, Leader et al. disclose a cartridge for analyzing blood wherein the device includes a peristaltic roller pump for pumping fluids. The peristaltic roller pump



Art Unit: 1641

includes a roller 206 that massages the pump tube 136. The roller 206 applies areas of alternating greater and lesser pressure to the pump tube 136, causing those portions of the pump tube 136 that lie over an area of greater pressure to be internally constricted and those areas of the pump tube 136 that lie over an area of lesser pressure to be relaxed to essentially the full unstressed diameter of the channel through the interior of the pump tube 136. As the roller 206 rotates, the areas of alternating greater and lesser pressure traverse the pump tube 136 to generate a peristaltic action in the pump tube 136. See column 8, lines 31-44.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to provide the peristaltic roller pump as disclosed by Leader et al. in the Vishnoi et al. device because Vishnoi et al. do not limit the type of pumping mechanism that can be used, and specifically state that positive and negative pneumatic pressure is illustrated but that other types of fluid pressure can be used (column 8, lines 9-16.) Thus the skilled artisan would have looked to the art for the various suitable pumping mechanisms, such as that disclosed by Leader et al., and modify the Vishnoi et al. device accordingly for incorporating the pumping mechanism. In such modification, the skilled artisan would have recognized that the channels within the Vishnoi et al. cassette are comparable to the pump tube of Leader et al. and thus can be substituted by the pump tube. Moreover, the skilled artisan would have recognized that the diaphragm on the Vishnoi et al. cassette can remain in the modified device since it forms the cassette. In the modified cassette and pumping mechanism, the pump tube is equivalent to the claimed tube forming a part of the circuit. The

Art Unit: 1641

diaphragm is equivalent to the claimed outer wall of the cartridge (cassette) for squeezing the pump tube beneath. The skilled artisan would have recognized that for the diaphragm to transfer the pressure to the pump tube, the tube can be disposed on the diaphragm (equivalent to the claimed outer wall.) (It is noted that in claim 13, the pump tube is also the "tube of the roller type tube pump"). Alternatively, the elastomeric membrane 232 is equivalent to the outer wall of the cartridge.

### ***Allowable Subject Matter***

Claims 15-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's election of the device and amendment of claims 15-22 to be directed to a device is acknowledged.

Applicant's newly added amendment regarding a concentration part for increasing a solute concentration from filtrate is addressed above in the newly cited art (Hedrick et al.)

Applicant also argues that Leader fails to disclose the use of an outer wall of a cartridge as a squeezing member or disposing a tube on an outer wall of a squeezing

Art Unit: 1641

member. The grounds for rejection have been clarified to point out where these limitations are taught or suggested by the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Thurs. 9-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/  
Primary Examiner, Art Unit 1641

Application/Control Number: 10/586,678  
Art Unit: 1641

Page 19